TALKING POINTS
PFIZER
November 2, 1981

I. Compliment Pfizer

A. Pfizer and other research intensive pharmaceutical companies are making a major contribution to the health and well being of the American people.

1. Pfizer's research and development program has brought us major new drug therapies. And it is my understanding that you will soon be marketing a number of important new drugs for cardiovascular disease and arthritis.

2. Pfizer's concentration on chronic diseases is particularly appropriate in light of the aging of the U.S. population. Every part of our health services system will be strained by this dramatic rise, between now and the year 2030, when over 18% of our population will be over 65. (In 1980, 11.2% were over 65.)

B. Given the exceptionally high increases in the cost of medical care during the last decade, it is important to note that price increases for drugs have been substantially lower.

1. During the last ten years the medical care component of the CPI has increased 117%, compared to a 45% increase for drugs during the same period.

II. Future of Pharmaceutical Development

A. It is my understanding that research intensive pharmaceutical companies are heading into an era of major new breakthroughs. Scientific advances are coming at an astonishing pace, particularly in areas like molecular genetics. Whether the new drugs of the next ten years will be as important as the introduction of sulfur drugs of the 1930's and penicillin drugs of the 1940's is to be seen. But the fact that we can forecast significant advances in drug therapy is a tribute to the men and women of Pfizer and the pharmaceutical industry.

III. Major Pharmaceutical Issues in Congress

A. Drug Approval Process

1. Many Members are concerned that the drug approval process at the FDA is delaying, unnecessarily, the introduction of new drugs. To the extent that this delay is not accompanied by commensurate gains in the safety and efficacy of drugs, the American public is the loser.

2. Congressman Scheuer, in particular, and Congressman Gore of the Energy and Commerce Committee have provided outstanding leadership in this area. As you know, they created a commission to study the FDA drug review process. I am also pleased to see that Commissioner Hayes has his own internal task force studing ways to improve FDA procedures and requirements. I look forward to the results of both these efforts.

B. Patent Term Restoration

1. One of the priorities of the PMA is legislation pending in the House of Representatives which would restore to a drug's patent term the number of years the drug was in the FDA approval process. I have held hearings on the issue, as has Congressman Kastenmeier.

2. While I believe it is imperative that we maintain strong incentives for pharmaceutical companies to invest substantial capital in research and development, I am concerned about this legislation:

a. We know that by extending the patent term of a drug we can expect a higher price for for a longer time for the drug, and increased revenues for the manufacturer.

b. Higher prices will have a relatively greater impact on the elderly.

c. If higher prices are essential to insure the continuing flow of significant new therapies, higher prices might be justified. <u>But</u> I am not yet confident that extended patent life and higher prices will translate into greater expenditures for research and development.

d. There are <u>many</u>, <u>many</u> factors influencing the

decisions to invest in research. The tie between that decision and patent term is not yet fully established.

C. Orphan Drugs

1. One of my greatest concerns is the development of orphan drugs. As you may know, bills to promote orphan drug development have attracted considerable attention in both Houses. (Weiss in House; Kassebaum in Senate) This is a disturbing problem; and its solution will require the coordinated efforts of the pharmaceutical industry, voluntary organizations and the government.

2. We must take whatever actions are necessary to increase our level of confidence that orphan drugs, when discovered, will be developed and made available.

3. The PMA's Commission on Drugs for Rare Diseases is an important step forward because it will provide an information clearinghouse for independent investigators. But more is needed if we are to overcome the barriers inhibiting orphan drug development.

4. The proponents of patent term restoration tell me it now costs $50 - $70 million to develop a new drug and that many important new therapies will <u>not</u> be forthcoming unless greater incentives are provided. If potentially profitable drugs will go undeveloped without new financial incentives, I have little confidence that unprofitable drugs for rare diseases will be developed under our current circumstances.

5. I am examining all possible options to improve the potential for orphan drugs. I welcome your imput.